PRVD2009-03

Proposed Re-evaluation Decision

# Aliphatic Alcohols

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# Overview

## What Is the Proposed Re-evaluation Decision?

After a re-evaluation of the aliphatic alcohols, Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is proposing continued registration of products containing aliphatic alcohols for sale and use in Canada.

An evaluation of available scientific information found that products containing aliphatic alcohols do not present unacceptable risks to human health or the environment when used according to the label directions. As a condition of the continued registration of aliphatic alcohols uses, new risk-reduction measures must be included on the labels of all products.

This proposal affects all end-use products containing aliphatic alcohols registered in Canada. Once the final re-evaluation decision is made, the registrants will be instructed on how to address any new requirements.

This Proposed Re-evaluation Decision is a consultation document[1] that summarizes the science evaluation for aliphatic alcohols and presents the reasons for the proposed re-evaluation decision. It also proposes additional risk-reduction measures to further protect human health and the environment.

The information is presented in two parts. The Overview describes the regulatory process and key points of the evaluation, while the Science Evaluation provides detailed technical information on the assessment of aliphatic alcohols.

The PMRA will accept written comments on this proposal up to 45 days from the date of publication of this document. Please forward all comments to Publications (please see contact information indicated on the cover page of this document).

## What Does Health Canada Consider When Making a Re-evaluation Decision?

The PMRA's pesticide re-evaluation program considers the potential risks, as well as the value, of pesticide products to ensure they meet modern standards established to protect human health and the environment. Regulatory Directive DIR2001-03, *PMRA Re-evaluation Program*, presents the details of the re-evaluation activities and program structure.

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1 Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

An aliphatic alcohol, one of the active ingredients in the current re-evaluation cycle, has been reassessed under Re-evaluation Program 1. This program relies as much as possible on foreign reviews, typically United States Environmental Protection Agency (USEPA) Reregistration Eligibility Decision (RED) documents. For products to be re-evaluated under Program 1, the foreign review must meet the following conditions:

- it covers the main science areas, such as human health and the environment, that are necessary for Canadian re-evaluation decisions;
- it addresses the active ingredient and the main formulation types registered in Canada; and
- it is relevant to registered Canadian uses.

Given the outcome of foreign reviews and a review of the chemistry of Canadian products, the PMRA will propose a re-evaluation decision and appropriate risk-reduction measures for Canadian uses of an active ingredient. In this decision, the PMRA takes into account the Canadian use pattern and issues (e.g. the federal Toxic Substances Management Policy [TSMP]).

Based on the health and environmental risk assessments published in a 2007 RED, the USEPA concluded that aliphatic alcohols were eligible for reregistration provided risk-reduction measures were adopted. The PMRA compared the American and Canadian use patterns and found the USEPA assessments described in this RED were an adequate basis for the proposed Canadian re-evaluation decision.

For more details on the information presented in this overview, please refer to the Science Evaluation of this consultation document.

## What Are Aliphatic Alcohols?

Aliphatic alcohols are plant growth regulators that are used to control tobacco suckers in tobacco plants. They act by physically burning the young sucker growth at each leaf axil touched by the spray solution. The aliphatic alcohols dissolve the layer of waxy cuticle on the epidermis, causing dehydration (burning).

## Health Considerations

### Can Approved Uses of Aliphatic Alcohols Affect Human Health?

**Aliphatic Alcohols are unlikely to affect your health when used according to the revised label directions.**

People could be exposed to aliphatic alcohols by inhaling smoke of treated tobacco and/or by consuming water from run-off in treated areas, while working as a mixer/loader/applicator or by entering treated sites. The PMRA considers two key factors when assessing health risks: the levels at which no health effects occur and the levels to which people may be exposed. The dose levels used to assess

risks are established to protect the most sensitive human population (e.g. children and nursing mothers). Only uses for which exposure is well below levels that cause no effects in animal testing are considered acceptable for continued registration.

The USEPA concluded that aliphatic alcohols were unlikely to affect human health provided that risk-reduction measures were implemented. These conclusions apply to the Canadian situation, and equivalent risk-reduction measures are required.

## Environmental Considerations

### What Happens When Aliphatic Alcohols Are Introduced Into the Environment?

**Aliphatic alcohols are unlikely to affect non-target organisms when used according to the label directions.**

Environmental risk is assessed by the risk quotient method—the ratio of the estimated environmental concentration to the relevant effects endpoint of concern. The resulting risk quotients are compared to corresponding levels of concern. A risk quotient less than the level of concern is considered a negligible risk to non-target organisms, whereas a risk quotient greater than the level of concern indicates some degree of risk.

The USEPA concluded that the reregistration of aliphatic alcohols was acceptable. The same conclusion applies to the Canadian situation. Furthermore, the PMRA will require both aquatic and terrestrial buffer zones to protect aquatic organisms and terrestrial plants from spray drift.

## Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law. As a result of the re-evaluation of aliphatic alcohols, the PMRA is proposing further risk-reduction measures for product labels.

**Human Health**

- Protective equipment to protect mixer/loader/applicators
- A restricted-entry interval to protect workers re-entering treated sites

**Environment**

- Buffer zones to protect non-target, sensitive terrestrial and aquatic habitats

## Next Steps

Before making a final re-evaluation decision on aliphatic alcohols, the PMRA will consider all comments received from the public in response to this consultation document. The PMRA will then publish a Re-evaluation Decision[2] that will include the decision, the reasons for it, a summary of comments received on the proposed decision and the PMRA's response to these comments.

2 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

# Science Evaluation

## 1.0 Introduction

The currently registered aliphatic alcohols consist of two active ingredients, 1-octanol and 1-decanol. Aliphatic alcohols are shoot inhibitors and are used as plant growth regulators on tobacco. They act by physically burning the young sucker growth at each leaf axil touched by the spray solution. The aliphatic alcohols dissolve the layer of waxy cuticle on the epidermis, causing dehydration (burning).

Following the re-evaluation announcement for aliphatic alcohols, the registrant of the technical grade active ingredient in Canada indicated that they intended to provide continued support for all uses included on the labels of commercial end-use products in Canada.

The PMRA used recent assessments of aliphatic alcohols from the USEPA. The USEPA RED document for aliphatic alcohols, dated March 2007, as well as other information on the regulatory status of aliphatic alcohols in the United States can be found on the USEPA Pesticide Registration Status page at www.epa.gov/pesticides/reregistration/status.htm.

## 2.0 The Technical Grade Active Ingredient, Its Properties and Uses

### 2.1 Identity of the Technical Grade Active Ingredient

| | |
|---|---|
| **Common Name** | Decanol |
| **Function** | Plant growth regulator |
| **Chemical Family** | Fatty alcohol |
| **Chemical Name** | |
| 1 **International Union of Pure and Applied Chemistry (IUPAC)** | Decan-1-ol |
| 2 **Chemical Abstracts Service (CAS)** | 1-Decanol |
| **CAS Registry Number** | 112-30-1 |
| **Molecular Formula** | $C_{10}H_{22}O$ |
| **Structural Formula** | |
| **Molecular Weight** | 158.28 atomic mass units |
| **Purity of the Technical Grade Active Ingredient** | 98% minimum |
| **Registration Number** | 24995 |

| | | |
|---|---|---|
| **Common Name** | Decanol (fatty acids present as n-Decanol)) | |
| | Octanol (fatty acids present as n-Octanol) | |
| **Function** | Plant growth regulator | |
| **Chemical Family** | Fatty alcohol | |
| **Chemical Name** | | |
| 1 **International Union of Pure and Applied Chemistry (IUPAC)** | decan-1-ol | (FAA) |
| | octan-1-ol | (FAB) |
| 2 **Chemical Abstracts Service (CAS)** | 1-decanol | (FAA) |
| | 1-octanol | (FAB) |
| **CAS Registry Number** | FAA 112-30-1 | |
| | FAB 111-87-5 | |
| | $C_{10}H_{22}O$ | (FAA) |
| | $C_8H_{18}O$ | (FAB) |
| **Structural Formula** FAA | | |
| FAB | | |
| **Molecular Weight** | 158.28 amu | (FAA) |
| | 130.23 amu | (FAB) |
| **Purity of the Technical Grade Active Ingredient** | 51% minimum | (FAA) |
| | 40% minimum | (FAB) |
| **Registration Number** | 24996 | |

For 1-decanol, based on the manufacturing process used, impurities of human health or environmental concern as identified in the *Canada Gazette*, Part II, Vol. 139, No. 24, SI/2005-114 (30 November 2005), including TSMP Track 1 substances, are not expected to be present in the product.

For the mixture of 1-decanol and 1-octanol, based on the manufacturing process used, impurities of human health or environmental concern as identified in the *Canada Gazette*, Part II, Vol. 142, No. 13, SI/2008-63 (25 June 2008), including TSMP Track 1 substances, are not expected to be present in the product.

## 2.2 Physical and Chemical Properties of the Technical Grade Active Ingredient

| Property | 1-decanol |
|---|---|
| **Vapour Pressure at 25°C** | 0.00851 mm Hg |
| **Ultraviolet (UV)–Visible Spectrum** | Not applicable<br>The product does not contain a UV chromophore. |
| **Solubility in Water at 20°C** | Insoluble |
| ***n*-Octanol–water Partition Coefficient** | Log $K_{ow}$ = 4.57 |
| **Dissociation Constant** | Not applicable<br>The product does not dissociate under normal conditions. |
| **Property** | **1-decanol, 1-octanol** |
| **Vapour pressure at 25°C** | 1-decanol: 0.00851 mm Hg<br>1-octanol: 0.0794 mm Hg |
| **Ultraviolet (UV)–visible spectrum** | Not applicable<br>The product does not contain a UV chromophore. |
| **Solubility in water at 20°C** | 1-decanol: Insoluble<br>1-octanol: 540 mg/L |
| ***n*-Octanol–water partition coefficient at 25°C** | 1-decanol: Log $K_{ow}$ = 4.57<br>1-octanol: log $K_{ow}$ = 3 |
| **Dissociation constant** | Not applicable<br>The product does not dissociate under normal conditions. |

## 2.3 Comparison of Use Patterns in Canada and the United States

Aliphatic alcohols are plant growth regulators registered in Canada to control suckers on tobacco. They are applied before topping at mid-button to late-button or early flower stage and after topping. Aliphatic alcohols are applied up to two times with an application rate of up to 14.4 kg a.i./ha on tobacco. The end-use products are formulated as a liquid, emulsifiable concentrate or solution and are applied using groundboom sprayer, hand-held or backpack sprayer.

The American and Canadian use patterns were compared. Based on this comparison of use patterns, it was concluded that the USEPA RED for aliphatic alcohols is an adequate basis for the re-evaluation of uses of aliphatic alcohols in Canada.

All current uses are being supported by the registrant(s) and were, therefore, considered in the re-evaluation of aliphatic alcohols. Appendix I lists all aliphatic alcohols products registered as of 17 October 2008 under the authority of the *Pest Control Products Act*.

## 3.0 Impact on Human Health and the Environment

In their 2007 RED, the USEPA concluded that the end-use products formulated with aliphatic alcohols met the safety standard under the American *Food Quality Protection Act* and would not pose unreasonable risks or adverse effects to humans and the environment if used according to the amended product labels.

### 3.1 Human Health

Toxicology studies in laboratory animals describe potential health effects resulting from various levels of exposure to a chemical and identify dose levels at which no effects are observed. Unless there is evidence to the contrary, it is assumed that effects observed in animals are relevant to humans and that humans are more sensitive to effects of a chemical than the most sensitive animal species.

In Canada, exposure to aliphatic alcohols may occur through consumption of water and inhalation of tobacco smoke, while working as a mixer/loader/applicator or by entering treated sites. When assessing health risks, the PMRA considers two key factors: the levels at which no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (e.g. children and nursing mothers).

#### 3.1.1 Occupational Exposure and Risk Assessment

Occupational risk is estimated by comparing potential exposures with the most relevant endpoint from toxicology studies being used to calculate a margin of exposure (MOE). This is compared to a target MOE incorporating safety factors protective of the most sensitive subpopulation. If the calculated MOE is less than the target MOE, it does not necessarily mean that exposure will result in adverse effects, but mitigation measures to reduce risk would be required.

Workers can be exposed to aliphatic alcohols when mixing, loading or applying the pesticide and when entering a treated site to conduct activities such as scouting and/or handling of treated crops.

It was determined that there were no acute endpoints of toxicological concern; therefore, the USEPA did not conduct quantitative occupational exposure and risk assessments. However, eye irritation studies resulted in severe and sometimes non-reversible eye irritation. Therefore, the USEPA required a restricted-entry interval (REI) of 48 hours for all aliphatic alcohols agricultural use products as per the Worker Protection Standard. A long-sleeved shirt, shoes plus socks and long pants were also required.

The RED adequately addressed exposure scenarios associated with the uses of products containing aliphatic alcohols in Canada, and conclusions derived from the RED apply to the Canadian situation. The PMRA requires label signal words on all aliphatic alcohol labels, including a 48-hour REI. Furthermore, workers are required to wear long pants, shoes plus socks and a long sleeved shirt during mixing/loading/applying. Proposed label amendments are listed in Appendix II.

### 3.1.2 Exposure from Food and Drinking Water

The USEPA does not consider the use of aliphatic alcohols on tobacco plants as a food use. Therefore, the USEPA did not conduct a dietary (food) risk assessment. It should be noted that these alcohols are listed as allowable food additives by the American Food and Drug Administration.

In Canada use on tobacco is considered as a food use. The PMRA concluded that there were no health concerns as the fatty alcohols are present in all natural tissues. Furthermore, it was considered unlikely the residues of fatty alcohol chains would survive the pyrolysis of the tobacco. The potential health risk associated with the inhalation of pyrolysis products from these fatty alcohols is unlikely to be increased when compared to the endogenous levels of fatty chains present in tobacco. On this basis, an assessment of exposure to aliphatic alcohols from the inhalation of tobacco smoke was not required by the PMRA.

The USEPA concluded that drinking water was not a concern due to the following considerations:

- lack of hazard for the oral route of exposure;
- lack of toxicological endpoints based on available data;
- the high vapour pressure of aliphatic alcohols products and their likely volatilization in air; and
- atmospheric degradation by reaction with photochemically produced hydroxyl radicals.

Therefore, the USEPA did not require a risk assessment of exposure to aliphatic alcohols from drinking water.

### 3.1.3 Aggregate Risk Assessment

Aggregate risk combines the different routes of exposure to aliphatic alcohols. The USEPA does not consider tobacco as a food use, and exposure to aliphatic alcohols from drinking water was not a concern. Therefore, aggregate risk assessment was not required by the USEPA. In Canada, a risk assessment of exposure from food was not required and exposure from drinking water was not deemed to be of concern; therefore, the PMRA considers that an aggregate risk assessment is not required.

### 3.1.4 Cumulative Effects

The USEPA has not determined whether aliphatic alcohols have common mechanisms of toxicity with other substances or whether they share a toxic metabolite produced by other substances. Therefore, it was assumed that aliphatic alcohols do not share common mechanisms of toxicity with other substances and a cumulative risk assessment was not required.

## 3.2 Environment

### 3.2.1 Environmental Risk Assessment

No environmental fate data are available for the aliphatic alcohols. The estimated half-lives for volatility from soil for 1-octanol and 1-decanol were 3.5 minutes and 1 minute, respectively. There is some uncertainty about the rate of volatility of 1-octanol and 1-decanol from plant surfaces, since aliphatic alcohols have an affinity for the waxy surfaces of plants. These volatility half-lives suggest that the aliphatic alcohols will not be available for long to expose non-target terrestrial animals or to be transported to surface water bodies in runoff. The model indicates aliphatic alcohols have a moderate tendency to bind to soils. The portion of applied chemical that binds to the soil will be subject to biodegradation, with estimated half-lives for 1-octanol and 1-decanol of 2.3 days. The portion of applied chemical that does volatilize is estimated to degrade in the air by reaction with hydroxyl radicals with half-lives of about 10 hours. Dissipation via volatilization will greatly reduce the amount of aliphatic alcohols reaching surface-water bodies, and aliphatic alcohols will volatilize from water as well as soil. These alcohols have the potential to bioaccumulate in fish, but their bioconcentration factors suggest low potential to bioconcentrate.

To assess the ecological risk of aliphatic alcohols to terrestrial and aquatic non-target plants and animals, the USEPA calculated risk quotients (RQs) based on appropriate toxicity endpoints and expected environmental concentrations (EECs), and compared the resulting RQs to the corresponding levels of concern (LOCs).

Risk assessments for birds and mammals were not performed because aliphatic alcohols were found to be practically non-toxic to birds and mammals on an acute oral basis. As a result, the potential for aliphatic alcohols to have adverse effects on birds and mammals was expected to be low. Chronic risk to birds and mammals was not expected due to the volatility of the aliphatic alcohols, which are listed as allowable food additives by the American Food and Drug Administration.

Aquatic EECs were estimated using the Tier II Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) simulation model.

The modelling was based on the anticipated levels of aliphatic alcohols following a single effective application taken after an interval of 3.45 minutes for octanol and 3 minutes for decanol. The estimates also took into account the amount of volatilization from the surface of the soil prior to runoff from a single application per season ranging from 9.92 kg a.i./ha to 17.64 kg a.i./ha. Acute RQs did not exceed LOC for freshwater fish (Fathead minnow),

freshwater invertebrate (Water flea), marine/estuarine fish (Bleak was used as a surrogate for marine organisms), marine/estuarine invertebrate (Harpacticoid copepod) and algae (*Scenedesmus subspicatus*).

For terrestrial plants, EECs were calculated based on an application rate of 22.22 kg a.i./ha, using a Tier I plant seeding emergence study data. The RQ for terrestrial plants did not exceed the LOC of 1.0.

The USEPA states that aliphatic alcohols do not present significant potential risks to both terrestrial and aquatic non-target plants and animals. The conclusions derived from the USEPA RED are considered relevant to the Canadian situation.

The PMRA calculated terrestrial and aquatic buffer zones using the most sensitive endpoints and a model, which is more conservative than the ones used by USEPA, to further minimize spray drift to non-target species during ground applications. Proposed label amendments are listed in Appendix II. Inputs to buffer zone models are described in Appendix III.

### 3.2.2 Toxic Substances Management Policy Considerations

The management of toxic substances is guided by the 1995 federal TSMP, which puts forward a preventive and precautionary approach to deal with substances that enter the environment and could harm the environment or human health. The policy provides decision makers with direction and sets out a science-based management framework to ensure that federal programs are consistent with its objectives. One of the key management objectives is virtual elimination from the environment of toxic substances that result predominantly from human activity and that are persistent and bioaccumulative. These substances are referred to in the policy as Track 1 substances.

The federal TSMP and PMRA Regulatory Directive DIR99-03, *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy*, were taken into account during the re-evaluation of aliphatic alcohols. The PMRA has reached the following conclusions.

- The *n*-octanol–water partition coefficients (log $K_{ow}$) are 3 for octanol and 4.57 for decanol. They are below the TSMP Track 1 cut-off criterion of ≥5.0. Aliphatic alcohols were not found to be persistent. Aerobic soil half-lives are 2.3 days, which are below the TSMP Track 1 criterion of 180 days. Aliphatic alcohols do not meet all Track 1 criteria; thus, they are not candidates for Track 1 classification.

- Based on a review of the available chemistry information (see Section 2.1), the technical products are not expected to contain impurities of toxicological concern as identified in Regulatory Directive DIR98-04 or TSMP track 1 substances as identified in Regulatory Directive DIR99-03, Appendix II.

Formulant issues are being addressed through PMRA formulant initiatives and Regulatory Directive DIR2006-02, *Formulants Policy and Implementation Guidance Document,* published on 31 May 2006.

## 4.0 Incidence Report

Starting 26 April 2007, registrants are required by law to report incidents, including adverse effects to health and the environment, to the PMRA within a set timeframe. Incidents are classified into six major categories including effects on humans, effects on domestic animals and packaging failure. Incidents are further classified by severity, in the case of humans for instance, from minor effects such as skin rash, headache, etc., to major effects such as reproductive or developmental effects, life-threatening conditions or death.

The PMRA will examine incident reports and, where there are reasonable grounds to suggest that the health and environmental risks of the pesticide are no longer acceptable, appropriate measures will be taken, ranging from minor label changes to discontinuation of the product.

There were no incident reports submitted for aliphatic alcohols as of 17 October 2008.

## 5.0 OECD Status of Aliphatic Alcohols

Canada is part of the Organisation for Economic Co-operation and Development (OECD), which groups 30 member countries and provides governments with a setting in which to discuss, develop and perfect economic and social policies. They compare experiences, share information and analyses, seek answers to common problems, and work to co-ordinate domestic and international policies to allow for consistency in practices across nations.

Based on the current available information on the status of aliphatic alcohols in other OECD member countries, it was found that 2 end-use products containing aliphatic alcohols are registered in Australia and 18 products containing aliphatic alcohols are registered in the United States.

As described earlier in this document, the United States, also an OECD member, assessed the registration of all uses of aliphatic alcohols in 2007 and concluded that using aliphatic alcohols as a pesticide does not result in unreasonable adverse effects to human health or the environment.

## 6.0 Proposed Re-evaluation Decision

The PMRA has determined that aliphatic alcohols are acceptable for continued registration with the implementation of the proposed risk-reduction measures. These measures are required to further protect human health and the environment. The labels of Canadian end-use products must be amended to include the label statements listed in Appendix III. A submission to implement label revisions will be required within 90 days of finalization of the re-evaluation decision.

## 7.0 Supporting Documentation

PMRA documents, such as Regulatory Directive DIR2001-03, and DACO tables can be found on our website at www.pmra-arla.gc.ca. PMRA documents are also available through the Pest Management Information Service. Phone: 1-800-267-6315 within Canada or 1-613-736-3799 outside Canada (long distance charges apply); fax: 613-736-3798; e-mail: pmra_infoserv@hc-sc.gc.ca.

The federal TSMP is available through Environment Canada's website at www.ec.gc.ca/toxics.

The USEPA RED document for aliphatic alcohols is available on the USEPA Pesticide Registration Status page at www.epa.gov/pesticides/reregistration/status.htm.

## List of Abbreviations

| | |
|---|---|
| a.i. | active ingredient |
| CAS | Chemical Abstracts Service |
| DACO | data code |
| EEC | expected environmental concentration |
| EXAMS | Exposure Analysis Modeling System |
| g | gram(s) |
| ha | hectare |
| IUPAC | International Union of Pure and Applied Chemistry |
| kg | kilogram(s) |
| $K_{ow}$ | *n*-octanol–water partition coefficient |
| $LC_{50}$ | lethal concentration to 50% |
| $LD_{50}$ | lethal dose to 50% |
| LOC | level of concern |
| m | metre(s) |
| mg | milligram(s) |
| mm | millimetre(s) |
| mm Hg | millimetre mercury |
| MOE | margin of exposure |
| MRL | maximum residue limit |
| OECD | Organisation for Economic Co-operation and Development |
| pH | -log10 hydrogen ion concentration |
| p*K*a | -log10 acid dissociation constant |
| PMRA | Pest Management Regulatory Agency |
| ppm | parts per million |
| PRVD | Proposed Re-evaluation Decision |
| RED | Reregistration Eligibility Decision |
| REI | restricted-entry interval |
| RQ | risk quotient |
| TSMP | Toxic Substances Management Policy |
| USEPA | United States Environmental Protection Agency |
| UV | ultraviolet |

# Appendix I Registered Products Containing Aliphatic Alcohols as of 17 October 2008

| Registration Number | Marketing Class | Registrant | Product Name | Formulation Type | Guarantee |
|---|---|---|---|---|---|
| 24995 | Technical | Cognis Canada Corporation | Lorol C10-98 | Liquid | 98% n-Decanol |
| 11581 | Commercial | Cognis Oleochemicals Canada Ltd. | Emtrol Ten Tobacco sucker control | Liquid | 722 g/L n-Decanol |
| 11498 | Commercial | Chemtura Canada co. | Delete Sucker Control Agent | Suspension or emulsifiable concentrate | 688 g/L n-Decanol |
| 11558 | Commercial | Fair Products Inc. | Fair Tac C-10 Tobacco Sucker Spray | Emulsifiable concentrate | 680 g/L n-Decanol |
| 12849 | Commercial | United Agri Products Canada Inc. | Pfizol-10 Tobacco Sucker Control Agent | Emulsifiable concentrate | 688 g/L n-Decanol |
| 14165 | Commercial | Drexel Chemical Company | Drexel Antak Contact Sucker Control Agent for Tobacco | Emulsifiable concentrate | 687 g/L n-Decanol |
| 24996 | Technical | Cognis Canada Corporation | Lorol C8-10 Special | Liquid | 51% n-Decanol, 40% n-Octanol |
| 11527 | Commercial | Cognis Oleochemicals Canada Ltd. | Emtrol Tobacco Sucker Control | Emulsifiable concentrate | 45.39% n-Decanol, 35.6% n-Octanol |

# Appendix II Label Amendments for Products Containing Aliphatic Alcohols

The label amendments presented below do not include all label requirements for individual end-use products, such as first aid statements, disposal statements, precautionary statements and supplementary protective equipment. Additional information on labels of currently registered products should not be removed unless it contradicts the label statements below.

A submission to request label revisions will be required within 90 days of finalization of the re-evaluation decision.

For technical products containing aliphatic alcohols, the following are required.

i) In the principal display panel: replace "DANGER – EYE IRRITANT" with

**DANGER – CORROSIVE TO EYES**

ii) The following statement must be included in the section entitled **PRECAUTION.**

**CORROSIVE** to the eyes. **DO NOT** get in eyes. Wear goggles when handling.

For commercial end-use products containing aliphatic alcohols, the following are required.

i) In the principal display panel, add "**DANGER - CORROSIVE TO EYES**"

ii) Add the following statements to the section entitled **PRECAUTION.**

**CORROSIVE** to the eyes. **DO NOT** get in eyes. Wear goggles when handling.

Wear long pants, shoes plus socks and a long-sleeved shirt, during mixing, loading, applying, cleaning and repair.

Do not re-enter the treated areas until 48 hours after application.

iii) Add the following statement to a section entitled **ENVIRONMENTAL HAZARDS.**

**TOXIC** to aquatic organisms and non-target terrestrial plants. Observe buffer zones specified under **DIRECTIONS FOR USE**.

iv) Add the following to the section entitled **DIRECTIONS FOR USE.**

Field sprayer application:
**DO NOT** apply during periods of dead calm. Avoid application of this product when winds are gusty. **DO NOT** apply with spray droplets smaller than the American Society of Agricultural Engineers (ASAE) coarse classification. Boom height must be 60 cm or less above the crop or ground.

**DO NOT** apply by air.

Buffer zones:
Use of the following spray methods or equipment **DO NOT** require a buffer zone: hand-held or backpack sprayer and spot treatment.

The buffer zones specified in the table below are required between the point of direct application and the closest downwind edge of sensitive terrestrial habitats (such as grasslands, forested areas, shelter belts, woodlots, hedgerows, riparian areas and shrublands), sensitive freshwater habitats (such as lakes, rivers, sloughs, ponds, prairie potholes, creeks, marshes, streams, reservoirs and wetlands) and estuarine/marine habitats.

| **Method of Application** | **Crop** | **Buffer Zones (metres) Required for the Protection of:** | |
|---|---|---|---|
| | | **Aquatic Habitat** | **Terrestrial Habitat** |
| Field sprayer | Tobacco | 1 m | 1 m |

# Appendix III Inputs to Buffer Zone Models

| Ground Use Data (from Canadian labels) | | | | |
|---|---|---|---|---|
| **Crop** | **Formulation Type** | **Method of Application** | **Number of Application** | **Maximum Application Rate** |
| Tobacco | Emulsifiable concentrate | Ground application | 2 | 14.4 kg a.i./ha |

| Model Input Data for Aquatic Buffer Zones (from 2007 RED) | | |
|---|---|---|
| Half life for aquatic buffer zones | 8.67 days | – |
| Most sensitive freshwater species $LC_{50}$ | Fathead minnow | 0.23 mg/L |
| Most sensitive estuarine/marine species $LC_{50}$ | Bleak | 0.72 mg/L |

| Model Input Data for Terrestrial Buffer Zones (from 2007 RED) | | |
|---|---|---|
| Half-life for terrestrial buffer zones | 3 days | – |
| Most sensitive terrestrial plant species $EC_{25}$ for vegetative vigour | Corn | 10 134.83 g/ha |

# References

## Studies considered in the Chemistry Assessment

## LIST OF STUDIES/INFORMATION SUBMITTED BY REGISTRANT

| PMRA Document Number | Reference |
|---|---|
| 1595124 | Technical Chemistry file FAA-HEE-2. Technical Chemistry file FAA-HEE-2. Henkel 3323 Lorol CIO-98 Decyl Alcohol N-decanol. Specifications and Analytical Methodology Required for Registration of Lorol CIO-98 as a Technical Active ingredient for Tobacco Sucker Control Agents. Includes Figures and Appendices. DACO 2.1, 2.11, 2.12, 2.13.1, 2.13.3, 2.14.1, 2.14.10, 2.14.12, 2.14.13, 2.14.14, 2.14.2, 2.14.3, 2.14.5, 2.14.6, 2.14.7, 2.14.8, 2.14.9, 2.2, 2.3, 2.4, 2.5, 2.6, 2.7, 2.8, 2.9 |
| 1595136 | Technical Chemistry file FAA/FAB-HEK-3. Correspondence with the Lab – n-Decanol/n-Octanol Technical |
| 257211 | Statement of Product Specification Form. DACO 0.1.6003 |
| 1522310 | Statement of Product Specification Form. DACO 0.1.6003 |
| 257229 | Statement of Product Specification Form. DACO 0.1.6003 |
| 257230 | Statement of Product Specification Form. DACO 0.1.6003 |
| 1666659 | Technical Chemistry for FAA/FAB-HEE-2. Specifications and Analytical Methodology Required for Registration of Lorol C8-10 as a Technical Active Ingredient for Tobacco Sucker Control Agents. DACO 2.1, 2.10, 2.11, 2.12, 2.13, 2.14, 2.2, 2.3, 2.4, 2.5, 2.6, 2.7, 2.8, 2.9. |
| 1666649 | Technical Chemistry for FAA/FAB-HEE-2. Emery Group, Analytical Applications Report. DACO 2.99. |